UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs/Counterclaim Defendants, v. MYLAN LABORATORIES LIMITED and MYLAN INC., Defendants/Counterclaim Plaintiffs.	Civil Action No. 3:12-cv-01378(MLC)(TJB) ***DOCUMENT ELECTRONICALLY FILED***

MYLAN'S OPPOSITION TO ASTRAZENECA'S APPEAL FROM THE MAGISTRATE JUDGE'S JULY 15, 2015 ORDER

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Defendants Mylan Laboratories Limited and Mylan Inc. (collectively, "Mylan") oppose the appeal of Plaintiffs' AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI INC., and KBI-E INC. (collectively, "AstraZeneca") from the Magistrate Judge's order prohibiting AstraZeneca from using certain testing evidence in support of its motion for preliminary injunction. AstraZeneca's appeal misstates the standard of review, the facts, and the relevant law in attempting to put off the date of a potential launch by Mylan. Under the proper framework, the Magistrate Judge's ruling should be affirmed.

I. THE MAGISTRATE JUDGE'S DECISION IS AFFORDED DISCRETION

As an initial matter, AstraZeneca is wrong about the applicable standard of review. While AstraZeneca argues that the Magistrate Judge's ruling should be overturned because it is "contrary to law," the determination is clearly a factual one, based on—as the Magistrate Judge herself pointed out—"the specifics of this case." ECF No. 172 at 1. As such, AstraZeneca has an extremely high burden in this appeal. As this Court has recently reiterated:

> The clearly erroneous standard of review applies to a magistrate judge's findings of fact. A finding of fact is clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed. The Third Circuit has interpreted this to mean that the appellate court must accept the factual determination of the fact finder unless that determination either (1) is completely devoid of minimum evidentiary support displaying some hue of credibility, or (2) bears no rational relationship to the supportive evidentiary data. Therefore, a district judge will not reverse a magistrate judge's decision even if the district judge would have decided the matter differently. In other words, a district judge's simple disagreement with the magistrate judge's findings is insufficient to meet the clearly erroneous standard of review.

Celgene Corp. v. Natco Pharma Ltd., No. 10-5197 (SDW) (SCM), 2015 WL 4138982, at *2 (D.N.J. July 9, 2015) (Hon. Susan D. Wigenton) (internal citations, quotation marks, and alteration marks omitted). In addition, the Magistrate Judge has discretion regarding issues of

case management. *See Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, No. 09-3125 FLW, 2011 WL 6722707, at *6 (D.N.J. Dec. 21, 2011) (Hon. Freda L. Wolfson). Whether to strike evidence based on prejudice or surprise is considered an issue of case management and reviewed as an abuse of discretion. *Id.* at *6 ("the Court notes that the Magistrate Judge's decision to strike Plaintiff's Supplemental Expert Report will be reviewed under the abuse of discretion standard. Indeed, contrary to Plaintiff's suggestion, because the matter before the Magistrate Judge was related to the ongoing management of a case in which he had been intimately involved, and was related to a case management Order entered by the Magistrate Judge, the Court finds that review under the abuse of discretion standard is proper") (citing *Bailey v. Viacom Inc.*, 435 F. App'x 85, 89 (3d Cir. 2011)).

II. MJ BONGIOVANNI REQUIRED ASTRAZENECA TO DISCLOSE ITS INFRINGEMENT CONTENTIONS IN ADVANCE OF THE FILING OF ITS PRELIMINARY INJUNCTION MOTION

The Magistrate Judge has been closely involved in the ongoing management of the case, *see* ECF No. 172 at 2 ("over the past few months, the [Magistrate Judge] has aggressively presided over the parties' settlement efforts . . . and also actively discussing what would happen should settlement fail"). As noted by the Magistrate Judge, "it became clear that should settlement discussion become unfruitful, as they have, Mylan anticipated potentially launching as soon as it received the required FDA approval, *i.e.*, on August 3, 2015." ECF No. 172 at 2.

In order to aid potential settlement and to ensure fairness should negotiations fall through, the Magistrate Judge supervised the exchange of information between the parties, resulting in a June 16, 2015, joint letter to the Magistrate Judge noting AstraZeneca's agreement to provide Mylan with a letter setting forth the basis for AstraZeneca's assertion of infringement. The purpose of full disclosure of the parties' litigation positions was both to facilitate assessment of any potential settlement *and* to allow for a full and fair consideration of any motion for

preliminary injunction. *Id.* ("the Court's discussions with the parties included what methods could be employed to address the ramifications of the looming launch date, including the need to resort to preliminary injunction motion practice"). Both parties were well aware of the purpose of this exchange, and AstraZeneca's assertions to the contrary are disingenuous. *See* ECF No. 159-2, ¶ 11 (AstraZeneca's expert stating "I have reviewed … a June 30, 2015 letter from Mylan's counsel to AstraZeneca's counsel. I understand that the letter was part of an exchange that the parties promised the Court for *the purpose of providing additional specificity to the positions on infringement* and validity likely to arise in the context of AstraZeneca's motion for a preliminary injunction").

To ensure proper consideration by this Court of a motion for preliminary injunction, the Magistrate Judge "was adamant that the parties recognize that should a preliminary injunction motion become necessary, the District Court be afforded sufficient time to address same." ECF No. 172 at 2. In addition to requiring the parties to exchange contentions, the Magistrate Judge set a briefing schedule for a motion for preliminary injunction, where AstraZeneca would file a preliminary injunction motion by July 9, 2015, Mylan would respond by July 20, 2015, and AstraZeneca would reply by July 24, 2015. Inherent in this expedited schedule, as well as the nature of the extraordinary relief of a preliminary injunction, was that the motion would not involve the assertion of new theories, but instead would be a formal presentation of established theories to this Court.

As a result of discussions among the parties and with the Magistrate Judge, on June 22, 2015, AstraZeneca sent a letter to Mylan purportedly laying out its infringement case, and in turn Mylan provided its invalidity positions in a letter to AstraZeneca. AstraZeneca's letter referenced only one testing method, Raman Spectroscopy. On July 9, 2015, however,

AstraZeneca submitted a motion for preliminary injunction that contained analysis from three previously undisclosed forms of testing: infrared spectroscopy ("IR"), Scanning Electron Microscopy ("SEM"), and Optical Microscopy. Recognizing that it was impossible to properly respond to this analysis in the schedule set by the Magistrate Judge, Mylan filed a letter brief the next day, July 10, 2015, asking the new analysis be struck from AstraZeneca's preliminary injunction papers. Over the next several days, the parties sent several letters to the Magistrate Judge explaining their positions on the issue and the Magistrate Judge held a hearing on the matter on July 14, 2015.

On July 15, 2015, after reviewing Mylan's initial motion, all of the "supplemental briefing," and "considering all of the arguments made in support of and in opposition to Mylan's emergent application," the Magistrate Judge granted Mylan's motion and "exercise[d] its discretion to strike AstraZeneca's references and arguments related to the IR, SEM, and Optical Microscopy testing." *Id.* at 1 (citing *In re Fine Paper Antitrust Litig.*, 685 F.2d 810 (3d Cir. 1982)). The Magistrate Judge exercised this discretion because she found "that the prejudice suffered by Mylan [by allowing the analytical testing to be considered] significantly outweighs any prejudice to AstraZeneca caused by the striking of same." *Id.* This decision was made in consideration of all of the arguments AstraZeneca makes on appeal, including "that it takes time to determine what testing should be performed and … to engage in said testing," and that "AstraZeneca did not receive Mylan's new samples until April 8, 2015." *Id.* at 2.[1]

[1] To the extent AstraZeneca has presented new arguments on appeal based on evidence not presented to the Magistrate Judge, those arguments should not be considered. *Celgene*, 2015 WL 4138982, at *2 ("under the clearly erroneous standard, a district court may not consider any evidence which was not presented to the magistrate judge") (citation and internal quotation marks omitted).

The Magistrate Judge recognized that "[t]o require Mylan to respond to these previously undisclosed analytical tests in 11 days would be patently unfair." *Id.* at 3. And because of the looming potential launch date of August 3, 2015, the Magistrate Judge recognized that "extending the briefing schedule would necessarily require this Court to also stay Mylan's ability to launch, effectively granting AstraZeneca the relief it[] seeks, albeit temporarily … Under the specifics of this case, such a result is unacceptable." ECF No. 172 at 3. The Magistrate Judge's decision, properly considering all of the facts and arguments, was proper and should be affirmed by this Court.

III. ASTRAZENECA'S APPEAL SHOULD BE DENIED

A. AstraZeneca's Unfair Surprise Prejudiced Mylan

AstraZeneca misrepresents the Magistrate Judge's reasoning and analysis. AstraZeneca frames the issue as one in which the Magistrate Judge struck testing evidence because AstraZeneca "did not mention them by name in an informal letter it sent Mylan." AZ Br. at 1. That is thoroughly inaccurate. As discussed above, the Magistrate Judge had been carefully managing the case both to facilitate potential settlement *and* to ensure fulsome consideration of a motion for preliminary injunction and resolution of same in anticipation of the August 3, 2015 potential launch date by Mylan. *See Reckitt Benckiser*, 2011 WL 6722707, at *6.

The issue raised by Mylan and ruled on by the Magistrate Judge is that AstraZeneca never raised the infringement theories it now argues entitle it to a preliminary injunction—in its June 22, 2015 letter, its infringement contentions, or otherwise. The Magistrate Judge struck the testing evidence because it was produced too late to properly be responded to by Mylan, and "the prejudice suffered by Mylan significantly outweighs any prejudice to AstraZeneca caused by the striking of same." ECF No. 172 at 1; *see also Reckitt Benckiser*, 2011 WL 6722707, at *8 (affirming Magistrate Judge's striking of supplemental report, noting "the Magistrate Judge

expressly held that Defendants' ability to cure the prejudice caused by the Supplemental Report imposed an undue burden in light of the pending . . . trial date").

Notwithstanding AstraZeneca's assertion that "No authority permits excluding AstraZeneca's testing evidence," AZ Br. at 7, there is ample authority. "[D]istrict courts have discretion to provide expedited [injunctive] relief where certain criteria are satisfied. It is well-established that a preliminary injunction is an extraordinary remedy reserved only for those cases where it is clearly warranted." *Apple, Inc. v. Samsung Electronics Co.*, 678 F.3d 1314, 1334 (Fed. Cir. 2012); *see also Ferring Pharm., Inc. v. Watson Pharm., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) ("Preliminary injunctive relief is an extraordinary remedy, which should be granted only in limited circumstances.") (citation and internal quotations omitted).

As such, this Court—and the Magistrate Judge in issues entrusted to her discretion—has wide latitude to determine what is proper to consider when ruling on a preliminary injunction. *See Reckitt Benckiser*, 2011 WL 6722707, at *6. Therefore, although the Federal Rules of Evidence do not strictly apply to a preliminary injunction, there is no requirement that a court consider prejudicial material that would not be admissible under Fed. R. Evid. 403. AstraZeneca's approach is the classic attempt to surprise its opponent with new evidence, which is anathema to proper litigation practice. *See* Fed. R. Evid. 403 (providing for exclusion of relevant evidence for, *inter alia*, unfair prejudice); *see also Reckitt Benckiser*, 2011 WL 6722707, at *8; *In re Gabapentin Patent Litig.*, No. CA 00-CV-2931 FSH, 2011 WL 1807448, at *4 (D.N.J. May 12, 2011) (Hon. Faith S. Hochberg) (first factor considered under Fed. R. Evid. 403 is "the prejudice or surprise of the party against whom the excluded evidence would have been admitted") (citing *Nicholas v. Pennsylvania State Univ.*, 227 F.3d 133, 148 (3d Cir. 2000)). The fact that this evidence is offered in support of the extraordinary and discretionary relief of a

preliminary injunction makes its late disclosure even more prejudicial. *See* ECF No. 172 at 3 ("While the Court understands that AstraZeneca would normally not have an obligation to disclose this type of testing prior to the service of its opening expert reports, normal circumstances are not at play here and the parties were well aware of that fact."); *see also Celegene*, 2015 WL 4138982, at *2 (Magistrate Judge's decision on amending invalidity contentions under local rules was reviewed under clearly erroneous standard).

Here, the Magistrate Judge noted that "[t]o require Mylan to respond to these previously undisclosed analytical tests in 11 days would be patently unfair." ECF No. 172 at 3. That ruling cannot be overturned unless it is an abuse of discretion, or based on clearly erroneous findings of fact. *See Celegene*, 2015 WL 4138982, at *2; *Reckitt Benckiser*, 2011 WL 6722707, at *6. It was neither.

B. The Magistrate Judge's Decision Was Proper

The Magistrate Judge was clear that she was not barring AstraZeneca's newly revealed evidence for good. ECF No. 172 at 3 ("To be clear, the Court is not precluding AstraZeneca from relying on same at the trial of this matter."). The Magistrate Judge, however, recognized that Mylan would need time to properly respond to AstraZeneca's new evidence. *Id.* As noted by the Magistrate Judge, the parties and the Court have been working on a deadline of August 3, 2015, the date on which it is anticipated that Mylan will receive FDA approval and could launch. *Id.* at 2. Because of this date and the unfair surprise discussed above, the Magistrate Judge recognized "there would be no way to extend the scheduled and provide the District Court adequate time to conduct a hearing and determine the preliminary injunction motion before the projected August 3, 2015 FDA approval date." *Id.* at 3. The Magistrate Judge, therefore, used her discretion regarding case management to not extend the briefing schedule on the preliminary injunction. *Id.*; *see also Reckitt Benckiser*, 2011 WL 6722707, at *8.

C. Any Delay Is a Win for AstraZeneca

Mylan is eager to provide the Court with the full facts and analysis of why AstraZeneca's motion for preliminary injunction should be denied. Any attempt by AstraZeneca to obtain a back door injunction by delaying the consideration of the preliminary injunction motion should also be rejected. As the Magistrate Judge found such delay "would necessarily require this Court to also stay Mylan's ability to launch, effectively granting AstraZeneca the relief it seeks …." ECF No. 172 at 3; *see also Reckitt Benckiser*, 2011 WL 6722707, at *8.

The quickly approaching August 3 date has been marked on everyone's calendars for months. The Magistrate Judge has done everything she can to make sure that this Court is able to properly consider and rule on a motion for preliminary injunction by that date. ECF No. 172 at 2 ("The Court was adamant that the parties recognize that should a preliminary injunction motion become necessary [failing settlement], the District Court be afforded sufficient time to address same."). The parties were therefore "on notice and had every incentive to lay their cards on the table with respect to the disclosures, theories and testing that would be relied upon." *Id.* AstraZeneca did not comply with this requirement, springing new evidence on Mylan without notice.

The Magistrate Judge struck AstraZeneca's new infringement testing precisely because its late disclosure undermined Mylan's ability to provide a timely and thorough response, and was therefore prejudicial under the tight time constraints associated with the extraordinary relief AstraZeneca seeks. Admitting the testing evidence that was struck as prejudicial on July 15 would be even more prejudicial to Mylan at this late date, as Mylan has not had any opportunity to address the stricken evidence on the merits. But, delaying a decision on AstraZeneca's preliminary injunction motion effectively grants AstraZeneca a continued hold on the Nexium

market and keeps a safe and effective, generic version from the public.[2] The Magistrate Judge recognized the prejudice to Mylan under either scenario and, as such, correctly struck AstraZeneca's new infringement testing evidence. AstraZeneca's present dilemma is one entirely of its own making.

IV. CONCLUSION

For the reasons detailed above, this Court should affirm the ruling of the Magistrate Judge striking the newly revealed testing evidence from being considered in the motion for preliminary injunction.

Dated: July 23, 2015

Respectfully submitted,

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[2] Faced with this Hobson's choice, Mylan will be prepared to address the stricken evidence—to the best of its ability and to the extent practicable under the circumstances—during Monday's hearing.

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